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09/978,457	10/16/2001	Joseph J. Chang	56301P579D	5126

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WOOD, HERRON AND EVANS  
2700 CAREW TOWER  
CINCINNATI, OH 45202

EXAMINER
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STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

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05/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/978,457

Applicant(s)

CHANG, JOSEPH J.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1, 6 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

In order to clear the record, the Examiner acknowledges the Applicant's election of Species A (Figure 1) with traverse. The traversal is on the grounds that no election is required because claims 1-11 are the only claims presented in this application which correspond to Species A. The Examiner acknowledges this but notes that the restriction was still proper to prevent Applicant from presenting claims drawn to Species B. The previous Examiner withdrew claims 8, 10, and 11 as being drawn to a non-elected species. The withdrawal was not warranted, as these claims are readable on both species. Therefore, claims 1-11 have been examined in the instant Office Action.

### ***Response to Arguments***

Applicant's arguments, see Appeal Brief, filed 6/16/2005, with respect to the rejection(s) of claim(s) 1-7 and 9 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references cited below.

### ***Claim Objections***

Claims 1, 6, and 7 are objected to because of the following informalities: In regards to claim 1, the word "top" should be "tip". In regards to claims 6 and 7, there is no antecedent basis for "blocking means" and "impeding means".

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Jagger et al. (4,781,692). See Figures 4-5 and the respective portions of the specification. Jagger discloses an apparatus comprising a needle cannula (100) having a distal point, a proximal end, and further having a shaft with a circumference, a tip protector (106) having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon, means (104) coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the tip protector, a gasket (112) coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft, and means (110) fixedly coupled to the needle cannula at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point, further comprising a flash chamber (118), wherein the gasket can be formed of an adhesive material cured by exposure to ultraviolet light or selected from the group of paraffin, polyester, and

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polyamide, wherein the impeding means comprises an irregularity that blocks the needle shaft from passing through the gasket opening, and wherein the irregularity is a crimp.

Claims 1 and 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Plassche (5,300,045). See especially Figures 4-7 and the respective portions of the specification. Plassche discloses an apparatus comprising a needle cannula (34) having a distal point, a proximal end, and further having a shaft with a circumference, a tip protector (38) having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon, means (44) coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the tip protector, a gasket (proximal opening of 38) coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft, and means (48) fixedly coupled to the needle cannula at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point, wherein the gasket can be formed of an adhesive material cured by exposure to ultraviolet light or selected from the group of paraffin, polyester, and polyamide, wherein the impeding means comprises an irregularity that blocks the needle shaft from passing through the gasket opening, wherein the irregularity is a crimp, and wherein the blocking means comprises a tab (44) to block the tip protector opening, the tab pivotably coupled to the tip protector and slidably engaging the needle cannula shaft, and wherein the tab is an anti-stick metal tab.

Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Woehr et al. (6,117,108). Woehr discloses an apparatus comprising a needle cannula (14) having a distal point, a proximal end, and further having a shaft with a circumference, a tip protector (40) having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon, means (42) coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the tip protector, a gasket (58) coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft, and means (61 or 60) fixedly coupled to the needle cannula at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point, further comprising a flash chamber (22), wherein the blocking means comprises a tab to block the tip protector opening, the tab pivotably coupled to the tip protector and slidably engaging the needle cannula shaft, wherein the tab is an anti-stick metal tab, and wherein the impeding means comprises an irregularity that blocks the needle shaft from passing through the gasket opening, wherein the irregularity is a crimp.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Brimhall (6,224,569). Brimhall discloses an apparatus comprising a needle cannula (31) having a distal point, a proximal end, and further having a shaft with a circumference, a tip protector (40) having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon, means (46a,b) coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point

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of the needle cannula within the tip protector, a gasket (43) coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft, and means (38) fixedly coupled to the needle cannula at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a predetermined distance from the needle cannula distal point, and further comprising a flash chamber (34), wherein the gasket can be formed of an adhesive material cured by exposure to ultraviolet light or selected from the group of paraffin, polyester, and polyamide, wherein the impeding means comprises an irregularity that blocks the needle shaft from passing through the gasket opening, wherein the irregularity is a crimp, and wherein the blocking means comprises a tab (46a,b) to block the tip protector opening, the tab pivotably coupled to the tip protector and slidably engaging the needle cannula shaft, and wherein the tab is an anti-stick metal tab.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall (6,224,569) in view of Shinohura (4,551,138). Brimhall discloses all of the limitations recited in claim 10 but fails to disclose that the tip protector is transparent. Shinohura discloses a tip protector (15) that is optically transparent so that the user can determine the status (used or unused, broken or capable of reuse) of the needle without having to

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remove the protector, thus greatly reducing the chances of a needle stick (column 3, lines 30-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the protector of Brimhall with the transparency disclosed by Shinohura to greatly reduce the chances of a needle stick.


### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
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